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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/535,817	06/01/00	SCHENK	D 00209-US-NEW

020350
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HM12/0921

EXAMINER	
TURNER, S	
ART UNIT	**PAPER NUMBER**
1647	4

DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action Summary

Application No.	Applicant(s)
09/585,817	SCHENK et al
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 11, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-57* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a pharmaceutical composition comprising an agent effective to induce an immune response against an amyloid component, classified in class 530, subclass 350.

II. Claims 11-25, drawn to a method of preventing or treating a disorder characterized by amyloid deposition by administering an agent effective to induce an immune response against an amyloid component classified in class 514, subclass 12.

III. Claims 26-28 drawn to a method of determining the prognosis of a patient by measuring immunoreactivity of the patient's serum against amyloid component, classified in class 424, subclass 9.2.

IV. Claims 29-39, 42-43, drawn to a method of preventing or treating a disorder characterized by amyloid deposition by administering an antibody that specifically binds to an amyloid component, classified in class 424, subclass 130.1.

V. Claims 40-41, drawn to a method of preventing or treating a disorder characterized by amyloid deposition by administering a nucleic acid encoding an antibody that specifically binds to an amyloid component , classified in class 514, subclass 44.

VI. Claims 44-57, drawn a pharmaceutical composition comprising an antibody that specifically binds to an amyloid component, classified in class 530, subclass 389.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and VI are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The pharmaceutical compositions of Group I and VI are defined by different chemical and physical characteristics.

Inventions I and II are related as product and process of use. However, the inventions are distinct because the agent of Group I as claimed can be used in materially different methods, such as in a method of raising antibodies, also the method of Group II can be practiced without the agent of Group I, such as by using antibodies against an amyloid competent.

Inventions VI and IV are related as product and process of use. However, the inventions are distinct because the antibody of Group IV as claimed can be used in materially different methods, such as it can be used diagnostically, also the method of Group IV can be practiced without the antibody of Group VI, such as by using an agent that induces an immune response against an amyloid component.

Inventions II-V are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different goals. The methods are distinct because each assay is performed for divergent purposes. The methods of inventions II, IV and V are methods of treating a disorder by using different pharmaceutical compositions, while the method of invention III determines the prognosis of a patient.

Inventions I and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups III-IV neither use nor produce the agent of group I.

Inventions VI and II-III, V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups II-III, and IV neither use nor produce the antibody of group VI.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Additional Restriction Requirement

2. The claims of Groups I-VI are drawn to a multitude of amyloid components, as recited in claims 3, 5, 13, 15, 34-35 and 49-50. This constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the amyloid components are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

Upon election of one of Groups I-VI, Applicant is additionally required to elect a single amyloid component, i.e Applicant must elect one amyloid component from each of claims 3, 5, 13, 15, 34-35 and 49-50, (depending on the inventive Group, which is elected). This requirement is not to be considered as a requirement of an election of species, since each of the compounds recited in

alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wedensday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
17 September 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud